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Comparing Community and Specialty Provider-Based Recruitment in a Randomized Clinical Trial: Clinical Trial in Fecal Incontinence[a]

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Abstract: Recruitment of participants to clinical trials remains a significant challenge, especially for research addressing topics of a sensitive nature such as fecal incontinence (FI). In the Fiber Study, a randomized controlled trial on symptom management for FI, we successfully enrolled 189 community-living adults through collaborations with specialty-based and community-based settings, each employing methods tailored to the organizational characteristics of their site. Results show that using the two settings increased racial and ethnic diversity of the sample and inclusion of informal caregivers. There were no differential effects on enrollment, final eligibility, or completion of protocol by site. Strategic collaborations with complementary sites can achieve sample recruitment goals for clinical trials on topics that are sensitive or known to be underreported. Res Nurs Health 33:500–511, 2010

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Recruitment of participants to clinical trials remains a significant challenge, with many studies failing to recruit the needed number of participants (Gallagher-Thompson et al., 2006). The focus of

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this clinical trial, fecal incontinence (FI), is a health problem with significant social stigma attached to it (Garcia, Crocker, Wyman, & Krissovich, 2005) and known underreporting (Bliss, Fischer, Savik, Avery, & Mark, 2004; Johanson & Lafferty, 1996; Sultan, Kamm, Hudson, Thomas, & Bartram, 1993). In addition, our preliminary work revealed FI is a problem that health care providers rarely code among primary diagnoses in the health care record (i.e., using either ICD-9 codes or within the text of their notes; Whitebird, Bliss, Hase, & Savik, 2006).

Recruiting community-living people to participate in a study about symptom management of FI using dietary fiber supplementation posed a complex challenge—how to reach a largely hidden population that is reluctant to self-identify with the focus of the research and that is difficult to track using the electronic heath record. In studies such as this, recruitment efforts often focus on convenience samples of easily accessible subjects, for instance, patients seen in specialty clinics affiliated with academic settings where the research is being conducted. Relying on a single recruitment source, however, narrows the population frame and heightens the risk that recruitment goals will not be met. An alternative approach is strategic collaboration between researchers in academic and community health settings to broaden the reach of the study and thus increase the potential for successful recruitment and greater generalizability of the findings. Given differences in organizational structure and size between academic and community health settings, different recruitment strategies, and methods are likely needed. Little is known, however, about which recruitment strategies are most successful in various types of clinical settings and whether they differentially affect the characteristics of people who enroll and complete participation in a randomized clinical trial.

There have been a number of reports on the factors associated with good and poor recruitment to clinical trials (Campbell et al., 2007; Sood et al., 2009; Watson & Torgerson, 2006), the effectiveness of particular strategies (Brealey et al., 2007; Mapstone, Elbourne, & Roberts, 2007; Monaghan et al., 2007), recruitment of specific populations such as women and minorities (Coleman et al., 1997; Harris et al., 2003; Hussain-Gambles, Atkin, & Leese, 2004), barriers to study recruitment (Baquet, Commiskey, Daniel Mullins, & Mishra, 2006; Ford et al., 2008; Ross et al., 1999), and recruitment costs (Chin Feman et al., 2008; Peck, Sharpe, Burroughs, & Granner, 2008). In two instances authors compared the impact of two specific recruitment strategies used in a single study on demographic characteristics and study outcomes and found no difference between the strategies compared (Geraets et al., 2006; Sherman et al., 2009). Folmar et al. (2001) looked at the effect of recruitment setting, a hospital versus community setting, on recruitment yields and costs. They found yields were higher for hospital-based recruitment, and costs were lower for community-based recruitment, but screening costs for community recruitment were higher. To our knowledge, ours is the first comparison of recruitment methods and yields between community and academic health care settings and for a health problem associated with social stigma.

The purpose of this paper is to compare recruitment methods and strategies used in a community-based primary health care setting and a medical specialty practice affiliated with an academic setting for a randomized controlled clinical trial examining the use of fiber therapy for symptom management in adults with FI. Specifically, we assess how the recruitment methods differed between the two settings, the differing strategies applied at each site and their outcomes relative to study entry and protocol completion, and whether participant characteristics differed between sites for those entering and completing the study protocol.

METHOD

Background: The Fiber Study

The Fiber Study was a randomized controlled clinical trial to investigate the effects of three dietary fiber representing different levels of fermentation on symptom management of FI. The study used a single-blind, prepost, between groups design. In a power analysis, we determined that a minimum of 40 subjects per group would result in power of 80% to detect a medium effect size with alpha set at .05. Recruitment occurred serially over a 5-year period, and the final sample size was 189. An initial screening for study eligibility was completed by the recruiters at each recruitment site by interviewing potential participants and reviewing their medical records for exclusionary diagnoses and procedures. A second more detailed screening interview was conducted by the University study implementation team. The baseline segment of the study served as the final eligibility screening; participants who were unable to perform the study procedures or did

not have two episodes of FI during the baseline segment were ineligible to proceed to the supplement phase.

We randomly assigned eligible participants to ingest the daily supplement which contained a placebo or 16 g of total dietary fiber/day. The fibers represent three levels of fermentability (highly, moderately, and minimally, respectively); they were gum arabic, psyllium, and carboxy-methylcellulose. The supplements were prepared as a small muffin and as a juice mixture that were ingested twice per day. The study protocol was organized into four segments totalling 52 days in length: 14 day for the baseline segment, 6 day for increasing the amount of fiber to the maximum dose, and 32 day for consumption of a steady amount of fiber, during which data collected during the last 14 day paralleled the baseline segment.

Participants were asked to complete a variety of data collection forms and surveys in addition to consuming supplements. These included a stool diary (14 day), diet record (14 day), symptom evaluation form (daily), supplement intake form (daily), and a quality of life survey (twice). They were instructed to watch for a color change in their daily stools following ingestion of a food dye marker. During the baseline and final data collection segments they were to collect all stools for the entire week. Data collectors/trainers made a home visit at least once per week to each participant, monitoring, encouraging, and assisting in completing study procedures. Participants received incentives of up to $300 for completing all procedures. Although the intervention, consuming a prepared supplement twice daily, is relatively simple, the protocol is complex because of activities required to promote intervention fidelity and experimental control, and procure stool samples for laboratory analyses of stools.

Settings

The study was a collaborative effort of the School of Nursing at the University of Minnesota, HealthPartners Research Foundation (HPRF) a research center affiliated with HealthPartners (HP), a nonprofit mixed-model health plan in the Twin Cities metropolitan area in Minnesota, and Colon and Rectal Surgery Associates, LTD (CRSAL) a private specialty practice affiliated with the University of Minnesota. The HPRF and CRSAL were the primary recruitment sites for the study. We accepted but did not actively recruit potential participants who were not patients of either HP or CRSAL who self-referred themselves to the study if the person's health care provider provided eligibility information.

HP serves a population of about 660,000 enrolees through both owned and contracted clinics. Recruitment efforts focused primarily, although not exclusively, on patients enrolled in the HP owned HP Medical Group that provides general medical services to 200,468 people at its 22 primary care clinics. CRSAL is a specialty private practice that has been affiliated with the University of Minnesota, Division of Colon and Rectal Surgery since its inception in 1963. It has a well established residency and research program and provides the majority of clinical education for the department. It has eight locations in the Twin Cities and offers specialized treatment of colon and rectal cancer; inflammatory bowel disease, including Crohn's disease and ulcerative colitis; pelvic floor problems, including FI, constipation and rectal prolapse; and anorectal disorders. The practice sees approximately 20,000 patients per year.

The significant differences between HPRF and CRSAL in organizational size and structure led the research team to decide that recruitment methods and strategies would be site-specific and determined by the principal site-investigators, who would be in the best position to understand the strategies that would work at their site based on organization and staff structure.

HPRF Recruitment Methods

Recruitment at HPRF was developed as a staged-approach using three recruitment methods (a) direct to participant (b) indirect through health care providers and other referrals, and, (c) identification of potential participants using administrative databases. By gradually rolling out the study across the multi-year timeline, we were able to evaluate each recruitment method and assess the effectiveness of the strategies used. A staged-approach also provided a steady, managed flow of potential participants into the study.

Direct recruitment involved the use of brochures and posters that were carefully designed and tastefully constructed recognizing the embarrassment and stigma associated with FI. These were placed in clinic settings such as waiting rooms, clinic examination rooms, or patient bathrooms. We also placed a short description about the study that resembled an advertisement in an issue of *HealthPartners Today*, a health plan publication that was sent to all 650,000 members in both contract and staff model clinics.

Indirect recruitment focused on reaching out to all HP providers such as clinical staff, physicians, and nurses for referrals. We attended staff meetings at each clinic to present the study and recruitment materials and to answer any questions. We created brief information sheets for physicians about the study that provided information about FI from results of an earlier study on prevalence of FI conducted at HPRF (Bliss, Fischer, & Savik, 2005). The study staff also developed a short write-up about the study for electronic newsletters within HP, one for all staff and one specifically directed to physicians. We made presentations to specialty providers, such as the Geriatric Division and the Geriatric Nurse Practitioners who serve patients in community living settings. When a referral was received from a physician, a cover letter signed by the study PI and the referring physician and a study brochure were sent to the patient; then the study coordinator followed-up with a telephone call.

The third recruitment method was use of administrative databases and identification of potential participants through the use of an ICD-9 code (786.6) for FI within the database. Exclusionary criteria were then applied that focused on secondary conditions (e.g., previous bowel resection or ulcerative colitis). At this time, the primary care physician making the diagnosis for the patient was also identified, and a brief letter describing the study was sent informing them that one of their patients was eligible for study participation. The letter also requested clarification of the patient's condition and asking them to co-sign the enclosed patient recruitment letter. The physician also received a study brochure, the fact sheet about FI, and the one-page information sheet. When received from the physician, the letter was sent to potential participants with a study brochure and post card to return within 2 weeks if they did not wish to be contacted by the study staff. Patients who did not decline participation were contacted by the study coordinator.

CRSAL Recruitment Methods

Recruitment at CRSAL used similar methods as those at HPRF (Table 1): administrative database review, direct to patient contact, and indirect recruitment through referrals by surgeons in the group. As a specialty practice treating patients for colon and rectal issues including FI, CRSAL had the advantage of being able to identify all patients in their system who had been diagnosed and were currently being seen for FI, or who had been treated for FI in the recent past. Overall there were five strategies developed within these two recruitment methods that focused on the organization's strengths, its smaller size (eight clinics and 17 specialists), and focused clinical practice that allowed it to accurately identify patients with FI.

The initial recruitment method involved review of the electronic medical record database for

Table 1. Recruitment Strategy by Site

Recruitment Strategy	HPRF–Community Health Maintenance Organization	CRSAL–University Affiliated Specialty Practice
Direct to participant	Brochures and posters in clinic waiting room, patient restrooms, and examination rooms	Brochures and posters in clinic waiting rooms and patient restrooms
	Study brief for placement in health plan magazine	In-person/phone contact by recruiter
Indirect through health care providers	Presentation of study at clinic staff meetings	Same
	Ongoing outreach to clinic staff including use of 1 page fact sheet	Email messages to physician partners
	Study write-up for electronic newsletters directed at physicians or nurses	
	Presentations to specialty and geriatric care providers	
Administrative databases	Review of databases for ICD9 codes and physician approval followed by mail contact	Medical record review database review with mail contact
		Electronic chart review for post biofeedback with mail contact

Note: HPRF, HealthPartners Research Foundation; CRSAL, Colon and Rectal Surgery Associates Ltd; ICD9 code 786.6 was used to identify patients with a diagnosis of FI in the administrative database.

patients who had been diagnosed and treated for FI using non-surgical treatments including medication and pelvic floor muscle rehabilitation (biofeedback training). This database was advantageous because it allowed investigators to begin recruitment at the start of the study while the community-based site developed their strategies. Patients were eligible if they were waiting to receive treatment, had been on a maintenance exercise program for at least 20 weeks, or had received treatment in the past that was unsuccessful and were no longer practicing biofeedback or pelvic floor muscle exercises. Records of patients with FI who did not qualify for another study being conducted at CRSAL were also reviewed for eligibility for the Fiber Study. Once eligible patients were identified, they were contacted via mail by the recruiter at the site with a brochure and letter from the site investigator inviting their participation in the study. CRSAL promotes its involvement in innovative clinical treatments that are only available though participation in clinical research studies, so patients are aware that they may be contacted about participation in clinical trials. Phone follow-up by the recruiter was conducted with qualified patients who did not respond to the letter.

The second recruitment method, direct recruitment to participants, focused on a unique feature of CRSAL, the Pelvic Floor Center. In the center, established in 2000, an in-depth assessment and treatment of pelvic floor problems including incontinence is conducted. Over 400 patients with a variety of pelvic floor problems are evaluated each month. Direct to participant recruitment included active recruitment through use of a study recruiter or staff nurses in this clinic setting. Direct to participant recruitment also included the use of brochures and posters in all CRSAL clinic settings; these were the same recruitment materials used within HP and were placed in the clinic waiting rooms and restrooms. The principal site investigator also presented the study at staff meetings and by email messages to physicians to encourage referrals.

Surgeons were emailed the same physician information sheet and bowel incontinence fact sheet sent to HP health care providers, and a study brochure. They were emailed periodic reminders about the study and asked to refer interested patients to the recruiter or team at the University.

Statistical Analysis

Summary statistics are presented as frequencies and percentages for categorical data and means with standard deviations for interval data. Frequencies for those who entered with those who completed and between sites were compared using a chi-square test of association. These same comparisons for interval data were accomplished using a *t*-test. Comparisons between ineligible, withdrew, and completed by site were assessed using an ANOVA with post hoc comparisons using Tukey's HDS for age. Gender was compared using a chi-square test of association with post hoc comparisons assessed by partitioning the chi-square as described by Agresti (1990).

RESULTS

Study recruitment was successful at both sites to achieve the desired sample size. As can be seen in Table 1, study recruitment varied by site, and total contacts with potential participants were much higher at HPRF, as expected due to the larger population. Figure 1 shows the flow of participants entering the study by site across the study recruitment period. More participants entered from CRSAL during the first 5 months, which was consistent with expectations and the ability of CRSAL staff to identify individuals meeting study criteria more rapidly. As HPRF implemented and tested recruitment strategies, higher numbers entered the study from this site.

The number of potential subjects declining participation or ineligible following the initial screening was higher at CRSAL (Table 2); this resulted in a smaller percentage of overall contacts referred to the implementation (University of Minnesota) team for further enrollment procedures and informed consent. Not all participants referred to the implementation team consented to participate or completed the study. Although CRSAL referred fewer patients, the percentage of the patients entering the study from their site was similar to that of HPRF; once patients had consented and enrolled in the study, attrition from the study protocol was also similar between the sites. Twenty-four individuals self-referred to the study but only one enrolled. This analysis uses data from participants recruited from the two main recruitment sites.

The recruitment strategies and methods employed at the community-based and specialty academic site varied based on organizational and other characteristics of the site. Table 3 presents the type of recruitment method used, the strategies employed based on the method, and the rates for recruitment, enrollment, and protocol completion. There were three main recruitment methods used:

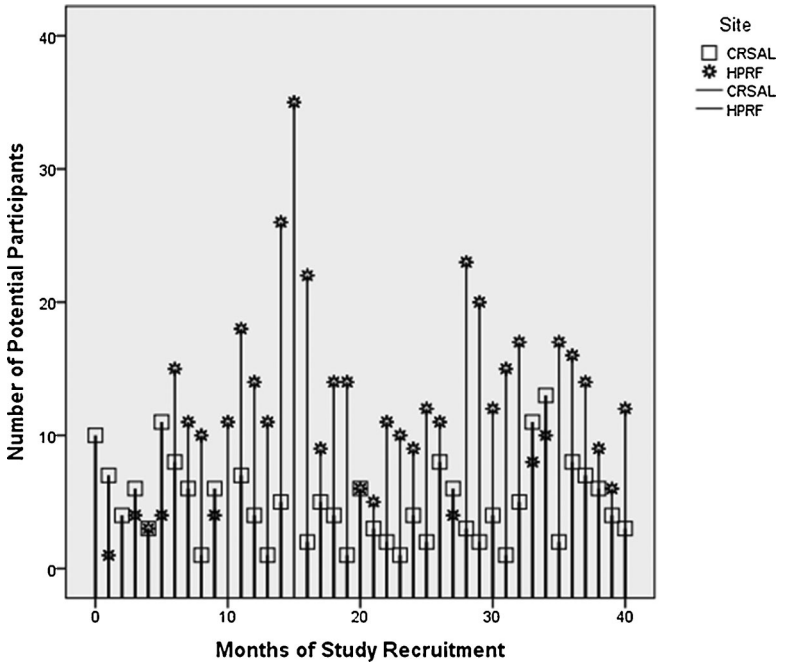

FIGURE 1. Circle represents actual count of potential participants at each month. The drop lines are to assist in lining the count up with its month.

direct to patient, indirect through heath care provider, and administrative database review. HPRF made use of each method, while CRSAL focused on direct to patient and administrative database review. At both sites multiple strategies were developed within each method designed to take best advantage of organizational characteristics relating to study recruitment, such as size or how much direct contact was possible with patients by study staff.

Direct to Patient Contact

Direct to patient recruitment using brochures and posters was employed at both sites; this strategy was more successful at HPRF, probably due to the greater number of clinics and patients visiting clinics at that site compared to the CRSAL site. This strategy also produced the highest volume of potential participants at HPRF compared to other strategies employed. This was not true at CRSAL,

Table 2. Recruitment by Site

Recruitment Contacts	HPRF *n* (%)	CRSAL *n* (%)
Total contacts (phone or letter)	674	475
Not interested/refused at initial screening	75/674 (11%)	152/475 (32%)
Ineligible per initial screening	126/674 (19%)	128/475 (27%)
Referred to implementation team	473/674 (70%)	195/475 (41%)[a]
Ineligible/not interested/unable to be recontacted at second screening	312/473 (66%) 152 (49%) ineligible 160 (51%) declined/ unable to be recontacted	128/195 (66%) 63 (49%) ineligible 65 (51%) decline/ unable to be recontacted
Entered protocol	161/473 (34%)	67/195 (34%)
Ineligible during baseline period	17/161 (11%)	6/67 (9%)
Withdrew after random assignment	11/144 (8%)	6/61(10%)
Completed protocol	133/144 (92%)	55/61 (90%)

Note: HPRF, HealthPartners Research Foundation; CRSAL, Colon and Rectal Surgery Associates Ltd.
[a] χ^2 (2, $n = 1149$) = 110.7, $p < .001$.

Table 3. Recruitment Outcomes by Site, Method, and Strategy

Recruitment Method	Strategy	Number Recruited Per Strategy	Referred to Implementation Team[a]	Entered Study[a]	Eligible After Baseline Period Screening[a]	Completed Study[a]
HPRF						
Direct to patient	Clinic poster/brochure	351	301 (86)	90 (26)	77 (22)	73 (21)
Direct to patient	Study brief in health plan magazine	126	83 (66)	36 (29)	34 (27)	31 (25)
Direct to patient	Word of mouth/other/self referral	36	21 (58)	9 (25)	8 (22)	7 (19)
Indirect though HC provider	Physician referral followed by phone contact	14	9 (64)	4 (29)	4 (29)	3 (21)
Indirect though HC provider	Health plan internal communication	25	16 (64)	7 (28)	6 (24)	5 (20)
Administrative database	ICD9 code & physician approval-mailed information	122	43 (35)	15 (12)	15 (12)	13 (11)
	Total	674	473 (70)[b]	161 (24)	144 (21)	133 (20)
CRSAL						
Direct to patient	Clinic poster/brochure	47	28 (60)	11 (23)	10(21)	9 (19)
Direct to patient	In-person (clinic) or phone contact by recruiter at pelvic floor center	146	44 (31)	13 (9)	12(8)	11(8)
Administrative database	Recruiter contact to patients not eligible for sacral nerve stimulator study	0	0	0	0	0
Administrative database	Electronic chart review for post biofeedback—mail contact	233	99 (43)	35 (15)	32 (14)	29 (12)
Administrative database	Medical record database review—mail contact	49	24 (49)	8 (16)	7 (14)	6 (12)
	Total	475	195 (41)[b]	67 (14)	61 (13)	55 (12)

Note: HPRF: HealthPartners Research Foundation; CRSAL, Colon and Rectal Surgery Associates Ltd. Rows drop off from cases initially identified and are not additive.
[a]Number and % of total recruited by each strategy.
[b]Percentages in row are of total recruited by all strategies at each recruitment site.

where administrative database review was far more successful in identifying potential participants. The additional direct to patient recruitment strategies employed were tailored to each site: a study brief in the HP magazine and word of mouth were used at HPRF; at CRSAL we used in-person communication and contact by a recruiter. In-person contact was far more successful at CRSAL than posters and brochures, perhaps due to the smaller number of clinics and a higher potential for direct patient contact. However, one of the CRSAL direct patient contact strategies, telephoning patients who were identified by their database record but did not respond to an initial recruitment mailing, was not successful. That strategy yielded no potential participants.

Administrative Database Review

Administrative database review was the most successful recruitment method at CRSAL, even though HPRF has a larger population base and thus larger administrative databases from which to draw. CRSAL, with its specialty focus linked to FI, proved more accurate at identifying potential participants with a higher percentage entering the study protocol following referral to the implementation team. The instance of diagnosis of FI at HPRF was relatively small given the population served, which may relate to the sensitive nature of FI and the reluctance of people to discuss this issue with their primary care physician. Physicians in HP and the HP Geriatric Division confirmed this observation when it was discussed with them. Specialty providers caring for this condition are in a better position to identify potential participants than non-specialty providers, and with greater accuracy, as can be seen by the success of this strategy at CRSAL compared to HPRF. Recruitment at specialty sites is often constrained by the smaller volume of patients seen in their clinics, as is reflected in the overall recruitment numbers.

Indirect Contact

The recruitment method of indirect contact through a health care provider was used at both HPRF and CRSAL, but did not yield any subjects at CRSAL. HPRF employed two strategies in this method, encouraging direct physician and other staff referrals using various internal electronic communication venues within HP; this also heightened awareness about the study in all HP clinic and administration settings. The overall number of potential participants identified was relatively small compared with the other two recruitment methods, but a higher percentage of those referred to the implementation team entered and completed the study compared to those referred through administrative databases at HPRF.

Participant Characteristics by Site

Given the different recruitment methods and strategies used and the populations served by each site, we examined whether these factors had any effect on the type of participants who entered the study and completed the protocol at each site. Table 4 presents demographic characteristics of those entering the study and completing the protocol at each site and also looks at whether participant characteristics differed between sites.

As can be seen in Table 4 there were no significant differences in participant characteristics between those who were eligible after the baseline segment to complete the study and did complete the study within each site, but there were some differences between the sites. HPRF provided a more diverse population by race and ethnicity for both entering and completing the protocol. All but one of the participants from CRSAL was white; one black participant was eligible after the baseline segment but did not complete the study: HPRF had 15 (9%) blacks eligible after the baseline segment, and 9 of them completed it. There were 10 (6%) participants grouped into a combined category, ''other,'' who were eligible after the baseline segment, and 8 completed the study. These included two American Indians (one completed), two Asians (two completed), two black/American Indian (one completed), three white/American Indian (three completed), and one white/black/American Indian (one completed). There were also three (2%) individuals of Hispanic ethnicity who eligible after the baseline segment and completed the study.

Caregiver status also differed between sites. Being a caregiver was self-reported and defined as being a primary caregiver for another family member or friend. There were higher numbers of participants who identified themselves as caregivers at HPRF than there were at CRSAL, and for a wider variety of relationships, including sibling and friend.

Table 5 displays demographic comparisons by site of the total number of potential participants

Table 4. Participant Characteristics Entering and Completing the Study Protocol by Site and Between Sites

	HPRF		CRSAL		Between Sites	
n (%)	Eligible After Baseline Segment	Completes Protocol	Eligible After Baseline Segment	Completes Protocol	*p*, Eligible	*p*, Completes
n[a]	144	133 (92%)	61	55 (90%)		
Age (mean (*SD*) years)	57.4 (14.2%)	57.2 (13.1%)	59.7 (13.1)	58.7 (13.1)	.29	.49
Age > 65 years	46 (32%)	40 (31%)	24 (39%)	20 (36%)	.31	.48
Gender: Female	104 (72%)	97 (73%)	51 (84%)	47 (86%)	.08	.07
Race/ethnicity						
Caucasian	128 (89%)	118 (89%)	59 (97%)	55 (100%)		
African-American	7 (5%)	7 (5%)	1(2%)	0		
Other	9 (4%)	8 (6%)	0	0	.15	.08
Hispanic ethnicity	3 (2%)	3 (2%)	0	0	.56	.63
Marital status						
Single	15 (11%)	15 (11%)	2 (3%)	2 (4%)		
Widowed	10 (7%)	10 (8%)	5 (8%)	3 (6%)		
Married	90 (65%)	86 (65%)	43 (72%)	42 (76%)		
Divorced	23 (17%)	22 (17%)	10 (7%)	8 (15%)	.38	.30
Employment						
Have employer	61 (45%)	59 (45%)	28 (42%)	27 (49%)		
Self-employed	12 (9%)	12 (9%)	3 (5%)	3(6%)		
Retired	63 (46%)	60 (46%)	29 (48%)	25 (46%)	.65	.67
Education						
< High School	2 (2%)	2 (1%)	2 (3%)	2 (4%)		
High school graduate	15 (11%)	15 (12%)	5 (8%)	5 (9%)		
Some college/Vo-Tech	58 (43%)	53 (41%)	20 (33%)	19 (35%)		
BS/BA degree	39 (29%)	39 (30%)	24 (40%)	23 (42%)		
Advanced degree	22 (16%)	22 (17%)	9 (15%)	6 (11%)	.46	.42
Provides caregiving[b]	44 (32%)	42 (32%)	9 (15%)	8 (14%)	.01	.01
Children	29 (21%)	28 (21%)	7 (12%)	6 (11%)	.11	.09
Spouse	13 (9%)	12 (9%)	1(2%)	1 (2%)	.05	.07
Parent	9 (7%)	9 (7%)	1 (2%)	1 (2%)	.15	.16
Sibling	1 (1%)	1 (1%)	0	0	1.0	1.0
Friend	2 (1%)	2 (2%)	0	0	1.0	1.0

Note: HPRF: HealthPartners Research Foundation; CRSAL: Colon and Rectal Surgery Associates Ltd.
[a]Demographic data of 10 of 17 subjects who were eligible after the Baseline segment but withdrew from the study are available.
[b]Caregivers may care for more than one person.

who were ineligible at any phase of the study, withdrew following the baseline segment and random assignment, and completed the study. More males were ineligible for participation at HPRF; ineligible candidates were younger at HPRF than at CRSAL. There were no differences in demographics by site of those who withdrew or completed the study.

DISCUSSION

The use of two diverse recruitment settings, each employing recruitment methods and strategies tailored to their organizational characteristics and size, benefitted the clinical trial. They enabled achievement of recruitment goals and increased the diversity of the sample without creating differential participant characteristics in those who entered or completed the study between sites, except for race and ethnicity. The increase in racial and ethnic diversity through HPRF was of particular importance given the historical exclusion of racial and ethnic minorities in clinical trials, the small percentage of minorities who reside in Minnesota, and the importance of including subjects of diverse race and ethnicity to the generalizability of study findings. The recruitment design was particularly successful in light of several challenges: the sensitive nature of the problem of FI, the difficulty in identifying the population, and enrolling participants into a

Table 5. Comparison of Recruits' Characteristics by Ineligible, Eligible-Withdrew, and Eligible-Completed

	HPRF			CRSAL		
	Total Ineligible	Withdrew	Completed	Total Ineligible	Withdrew	Completed
n	312/473 (66%)	11	133	128/195 (66%)	6	55
Male gender	33%[a]	36%	27%	15%[a]	50%	18%
Age mean (*SD*) years	57.6 (17.6)[b]	58.5 (18.1)	57.5 (14.1)	61.5 (14.6)[b]	70.8 (11.1)	60.8 (12.8)
Hispanic			2%			0
Race						
White		91%	88%		80%	100%
Black		0	5%		20%	0
Other		0	2%		0	0
More than 1 race		9%	4%		0	0
Employment						
Has employer		40%	45%		20%	49%
Self-employed		0	9%		0	6%
Not employed		60%	46%		80%	45%
Marital status						
Single		0	11%		0	4%
Married		0	8%		40%	6%
Widowed		80%	65%		20%	76%
Divorced		20%	17%		40%	15%

Note: HPRF, HealthPartners Research Foundation; CRSAL, Colon and Rectal Surgery Associates Ltd.
[a] $p < .001$.
[b] $p = .59$.

clinical trial with a rigorous protocol that requires random assignment to a placebo, daily ingestion of a diet supplement, daily data reporting tasks, and collection of entire stools.

Stigmatized health problems such as FI for which there is a high level of embarrassment and isolation, reluctance of patients to seek care and clinicians to inquire about the problem (Bliss, 2004; Gordon et al., 1999; Johanson & Lafferty, 1996) can create challenges to recruitment for a clinical trial. Identifying potential participants through a specialty-based provider affiliated with an academic setting can produce a readily available convenience sample with a fairly high degree of accuracy in identifying eligible participants, as was shown by recruitment results from the CRSAL site. The higher percentage of patients from CRSAL who were ineligible during the initial screening may have been a result of access to detailed and relevant medical information of potential participants and, hence, greater precision of their screening process. If we had relied solely on this site as its only recruitment venue, however, recruitment goals would not have been met within the funding period of the study as only approximately one-third of the final study sample came from CRSAL. Reliance on specialty/academic practices may be the Achilles heel for some clinical trials, especially if the topic is a sensitive one, as perceiving access to subjects as easy may lead to overly optimistic projections of potential numbers, and in part account for the high number of studies not meeting their recruitment goals (Adams, Silverman, Musa, & Peele, 1997). The findings may provide a template for the effort needed by these types of recruitment sites to reach their goals. To refer one patient to the study, CRSAL needed to contact 2.4 patients, and HP needed to contact 1.4 patients. For one subject from their site to complete the study, CRSAL needed to contact eight patients and HP needed to contact five. It should also be noted however, that a multi-step recruitment procedure required additional effort on the part of the study implementation team at the University, as more than half of those referred by either recruitment site were ultimately determined to be ineligible.

Although academic health settings can engage in successful communication strategies such as print and radio, or web advertising to reach potential subjects (Smith, Eubanks, Petrik, & Stevens, 2007), this may be a more challenging for a sensitive topic such as FI where the social stigma is great and mentioning the topic in public can be seen as taboo. Reaching out to people where they receive their health care and expect a variety of health topics to be addressed provides a safe and acceptable venue to discuss research opportunities

for health issues that potential participants prefer to keep private. This finding is supported by previous literature (Baquet et al., 2006; Sood et al., 2009) that potential participants who receive information from through their health care provider are significantly more likely to participant in clinical trials.

By seeking the collaboration of two diverse sites, each bringing unique strengths to study recruitment, the recruitment pool for this study was increased. Strategic collaboration in this case included allowing sites to choose strategies that they perceived would be most successful for their site based on organizational structure and size. As was seen in the results, the most successful strategy at HPRF, direct to patient use of brochures and posters, was the least successful at CRSAL; and the strategy that was most successful at CRSAL, use of administrative database, was less successful at HPRF, even with its much larger administrative database and population served. Also, indirect contact at HPRF, although providing a relatively small percentage of patients to the study, also had a higher percentage referred to the implementation team, eligible, and entering and completing the study, making this a valuable addition to the overall recruitment strategy at this site. Designing feasible recruitment strategies within an organization requires intimate knowledge about group structure and function, and as shown by results of this study, this can vary greatly between organizations.

Findings also show that similar to other studies using a variety of recruitment techniques (Geraets et al., 2006; Sherman et al., 2009) the use of these various recruitment methods and strategies had little effect on the characteristics of people enrolling in the study at each site, with one important distinction in our study; the use of the community site significantly increased the diversity of the study sample, an important positive benefit to the study. This supports the previous literature on minority recruitment that clinical trials need to reach out into the community where minority participants receive their services (Ford et al., 2008; Gallagher-Thompson, Solano, Coon, & Arean, 2003). Our results also show that there was only one additional significant difference in participant characteristics between those who entered the study, were eligible to complete the protocol, and who completed the protocol within and between sites: being a caregiver for a family member or friend. There were higher numbers of participants who identified as a caregiver at the HPRF site. These caregivers also were providing care for a more diverse group of care recipients, such as siblings and friends, than those from the CRSAL site. This result may be reflective of the increased diversity of the sample at the HPRF site, with many ethnic groups placing great attention on close as well as extended family relationships.

The results indicate that study recruitment for clinical trials on sensitive topics with rigorous protocols can be accomplished with successful collaborations that reach from academic health centers to specialty providers and community based health care settings. Each setting brings strengths to the recruitment plan that can complement the other. Specialty settings ''jump start'' study implementation and are more likely to accurately identify potential participants seen in their clinics for the condition under study. Community health care settings can reach out to potential participants through their regular health care settings and providers, identifying participants who may not otherwise find out about the research and potentially increasing the diversity of the sample, as well as providing more continuous referral of potential participants.

There is a pressing need in the research community to identify successful recruitment methods and strategies to increase success in clinical trial completion. This study is an example of how that can be accomplished. In order to increase the diversity of minority populations represented in clinical trials, strategies to reach out into the community are recommended. Collaboration and use of diverse recruitment settings can enhance the likelihood for successful recruitment in clinical trials of a sensitive nature. Establishing and maintaining collaboration requires intentional commitment and leadership of the investigators, but the rewards can be great.

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